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FEB – 6 2009

510(k) Summary
for
Maxx Orthopedics Freedom® Total Knee System

1. SPONSOR

Maxx Orthopedics, Inc.
2260 Butler Pike
Suite 100
Plymouth Meeting, PA 19462

Contact Person: Nach Dave
Telephone: 732-718-1385

Date Prepared: January 14, 2009

2. DEVICE NAME

Proprietary Name:	Freedom® Total Knee System
Common/Usual Name:	Total Knee Replacement
Classification Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

3. PREDICATE DEVICES

- Biomet Ascent Femoral and All-Polyethylene Tibial Bearing Knee System (K021559, K982869)
- Howmedica Osteonics Scorpio Femoral and Tibial Components, (K032829, K030978, K042343, K071991, K051977).

4. DEVICE DESCRIPTION

The Freedom® Total Knee System is comprised of a femoral component (cruciate retaining and posterior stabilizing), all-poly tibial component and a patellar component as described below.

The Freedom® Total Knee System's Femoral component is offered in both cruciate retaining and posterior stabilizing designs. The Femoral components are available in right and left configurations, and eight sizes to accommodate varying anatomy. The Freedom® Total Knee System's Femoral Component is made of Cobalt-Chromium-Molybdenum and is intended for cemented application to replace the articulating surface of the distal femur in a measured resection.

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The Freedom® Total Knee System's Tibial baseplate component is fabricated from ultra high molecular weight polyethylene and is intended for cemented application to replace the articulating surface of the proximal tibia in a measured resection. Both the Total Knee System CR and PS Tibial Inserts have identical locking mechanisms to mate with the Tibial Base Plate. The Freedom® Total Knee System Patellar component is available in a symmetric design fabricated from industry standard UHMWPE (ASTM F648). Testing of the Freedom® Total Knee System has been performed out to 135 degrees which demonstrates high flexion of the total knee device.

5. INTENDED USE

The Freedom® Total Knee System consists of a femoral component, tibial base plate, and a patellar component. The Freedom® Total Knee System is indicated for patients with severe knee pain and disability due to:

- Severe knee joint pain, loss of mobility, and disability due to: rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Correction of functional deformities.
- Post-traumatic loss of knee joint contour, particularly when there is patellofemoral erosion, dysfunction, and/or prior patellectomy.
- Moderate valgus, varus, or flexion trauma.
- Knee fractures untreatable by other methods

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed Freedom® Total Knee System and the predicate devices are identical in that they all consist of tibial baseplate components and/or femoral component, and patella components. Both the Freedom® Total Knee System femoral component and the predicate femoral component are manufactured from Cobalt-Chromium-Molybdenum. Both the proposed and predicate tibial components are made from ultra high molecular weight polyethylene. Both the proposed and predicate device patella components are made from UHMWPE.

Both the proposed product and the predicate devices have been designed to mimic the normal knee geometry. Both the proposed and predicate devices are available in a variety of femoral sizes, tibial sizes and patella sizes that are intended to mimic normal human anatomy. The articulating surface of the proposed Freedom® Total Knee System femoral and tibial components, are similar to the articulating surface of the predicate systems and are functionally equivalent devices. Both the proposed and

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predicate devices are made of biocompatible materials and are designed similarly to the predicate devices.

7. PERFORMANCE TESTING

Evaluations were performed to determine the material and mechanical characteristics of the Freedom® Total Knee System according to the Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA. This testing shows that the Freedom® Total Knee System functions as intended and is safe and effective for its intended use. The testing was performed to demonstrate the mechanical characteristics of the Freedom® Total Knee System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2009

Maxx Orthopedics, Inc.
% Medical Device Consultants, Inc.
Ms. Mary McNamara-Cullinane
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K082019
Trade/Device Name: The Freedom® Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: January 14, 2009
Received: January 15, 2009

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082019

Device Name: The Freedom® Total Knee System

Indications for Use:

The Freedom® Total Knee System consists of a femoral component, poly tibial component, and a patellar component. The Freedom® Total Knee System is indicated for patients with severe knee pain and disability due to:

- Severe knee joint pain, loss of mobility, and disability due to: rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Correction of functional deformities.
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- Moderate valgus, varus, or flexion trauma.
- Knee fractures untreatable by other methods

This system is intended for cemented use only.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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